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PCT/GB2004/004006



INVESTOR IN PEOPLE

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Newport  
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NP10 8QQ

REC'D 06 OCT 2004

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I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

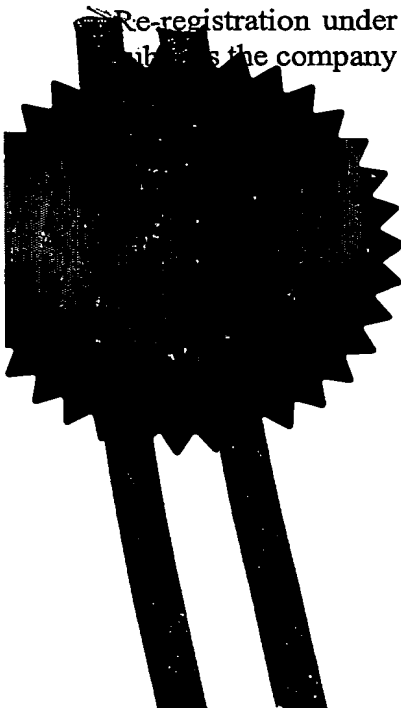
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Dated 26 September 2004



Patents Act 1977  
(Rule 1)

Patent  
Office

22SEP03 183840-1 002904  
P01/7700 G.00-0322099.3

**Request for grant of a patent**  
(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

GOVERNMENT  
THE PATENT OFFICE  
F  
20 SEP 2003  
NEWPORT

The Patent Office

Cardiff Road  
Newport  
Gwent NP9 1RH

20 SEP 2003

1. Your reference

METHOD FOR THE REDUCTION OF HAEMATOCRIT EFFECTS IN TEST STRIP AND BIOSENSORS

2. Patent application number

(The Patent Office will fill in this part)

0322099.3

3. Full name, address and postcode of the or of each applicant (underline all surnames)

08717282001

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

CAMBRIDGE SENSORS LTD

UNIT 9

CARDINAL PARK

GODMANCHESTER

HUNTINGDON

CAMBS

PE 29, 2XG

UK 266 8392

4. Title of the invention

5. Name of your agent (if you have one)

- N/A -

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

CAMBRIDGE SENSORS LTD

as above

Patents ADP number (if you know it)

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number  
(if you know it)

Date of filing  
(day / month / year)

N/A

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing  
(day / month / year)

N/A

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

- a) any applicant named in part 3 is not an inventor, or
  - b) there is an inventor who is not named as an applicant, or
  - c) any named applicant is a corporate body.
- See note (d))

YES

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description

Claim(s)

Abstract

Drawing(s)

1  
✓  
2  
0  
0  
0

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

N/A

11. Please note this is the original document, not a photocopy. G. McLann

I/We request the grant of a patent on the basis of this application.

Signature

Date

G. McLann  
G. McLann  
G. McLann

19<sup>th</sup> Sept 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

J. McCann

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- 1) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- 2) Write your answers in capital letters using black ink or you may type them.
- 3) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- 4) If you have answered "Yes" Patents Form 7/77 will need to be filed.

Tel 01480-482920 Fax 01480-482921

### Method for the Reduction of Haematocrit Effect on Test Strips and Biosensors

This invention relates to the use of a reagent on biosensor strips to reduce the unwanted effect of haematocrit effects on the test strips.

Saponin has been widely used as a lysing agent in diagnostic and analytical procedures. However in this reagent is combined with a second faster acting agent such as digitonin or DNMG (Decanoyl-N-Methylglucamide) to produce a lysing agent that is more rapid. This is of use in strips that have very fast reaction times.

Preferentially the reagent may be combined with, and also contain:

- An enzyme of choice (e.g. glucose dehydrogenase, or other red ox enzyme)
- A hydrophilic polymer (e.g. PVA, PVP, carboxy-methyl cellulose)
- A buffer and/or stabiliser

The reagent may be made up in an aqueous or organic solution and then dosed onto an electrode to form or complete the working electrode of a biosensor. In this manner a member may be formed that reduces the interfering effect of whole blood on the device.

Reagent may be applied to a device by any of the known methods in the art including, but not limited to screen printing, close proximity dosing, ink-jet printing, lithography, spray coating.

The reagent is applied to the electrode surface and then typically air dried at temperatures of between 40-60C until dry.

The reagent may be applied to devices fabricated by a number of means including screen printed electrodes, etched micro-arrays, thin film electrodes.

A mediator or co-factor compound may also be included in the reagent. Alternatively the co-factor and /or mediator may be applied directly onto the biosensor surface.

Devices can be constructed using methods available in the art that have very small fill volumes (down to 10-50nL) and fast reaction times.

**Example 1:** A mediator such as Meldola Blue is dosed onto an electrode surface. A screen printed layer of carbon, graphite, polymers and co-factor is screen printed over the electrode. A reagent as described above is then dosed onto the electrode containing PVP, glucose dehydrogenase and saponin/DNMG. The device may be completed by applying a mesh structure as described in US 6436256 or a capillary fill chamber.

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